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EXAMINER

MACHUGA, JOSEPH S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3762

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,154

Applicant(s)

WARIAR ET AL.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

Applicant's arguments have been carefully considered but are not deemed persuasive.

The WO 99/24145 document discloses:

"An apparatus for detecting dislodgement of a needle" as noted in the abstract, lines 4 and 5 where it states, "If the fistula needle (15, 19) becomes detached from the patient (8) the electrodes (A, B) will sense the leakage of blood and a signal is sent to the computer control and alarm system..."

"A sensor capable of detecting wetness..." Also noted in the abstract on line 5 where its states "the electrodes (A, B) will sense the leakage of blood..." and finally;

"A sensor holder adapted to secure the sensor in juxtaposition to the needle" which as illustrated in the either Figure 2 or 3 the holder (40/50) secures the sensors next to or in juxtaposition to the needle.

Therefore, all of the feature recited in the independent claims 1, 15 and 17 appear to be disclosed by this reference. The adhesive patch or cuff would hold the sensors both through adhesive and through friction. Accordingly, it is believed all the claimed features in the independent claims 1, 15 and 17 are provided for by this document. Regarding

the appropriateness of the Johnson reference. The document discloses one of many different types of fluid sensors that can be used to detect the presence of liquid. While the fluid in the instance is not blood it is still considered relevant since it is a biological fluid. Also, one skill in the art would obvious be aware of the numerous types of biological fluid sensors available as evidenced by the extent of the documentation in this area. Finally, since dislodgement of needles during dialysis is a life threatening situation it is considered obvious to use the Cox detector not only after surgeries but also with dialysis. Therefore the motivation to combine Cox and WO 99/24145 would be present. For these reasons the rejection of the claims is considered proper.

Applicants amendment to the drawing and corresponding text is considered sufficient to overcome the prior objection to the drawings. The amendment to claims is sufficient to overcome the rejection under 35 USC112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2, 7-10, 15, 17,18 and 23-26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/24145. Regarding claim 9 and 25 the control device

is attached to the patient through lines 13, 17, 42A and 42B as clearly illustrated in Figure 1.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 27-29, 30-34, 36, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145. As illustrated in Figures 2 and 3 the sensor includes a cutout portion enabling it to be added to the patient after the needle has been inserted. Given this, it would have been obvious to one of ordinary skill in the art to position the sensor on the patient *after* the needle is in place since it is one of two obvious and readily apparent possibilities and since this arrangement would allow for a clear unobstructed view of the vein which would not be the case if the sensor was already in place.

4. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145 as applied to claim 33 above, and further in view of either WO 97/10013, Shintani et al or JP 104233,

5. WO 97/10013, Shintani et al and JP 104233 all teach closing a control a valve in response to blood leakage. WO 99/24145 teaching that if leakage is detected corrected action to minimize blood lose should be taken (column 7, lines 15-18.)

6. It would have been obvious to one of ordinary skill in the art to shut off a clamp/valve in the fluid line of the WO 99/24145 device when a leak is detected given that WO 99/24145 suggests that corrective actions should take place in response to blood loss and given that it is old and well known to close a clamp/valve given the teachings of either WO 97/10013, JP104233 or Shintani et al.

7. Claims 3, 4, 8, and 9, 16, 19, 20, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145 in view of Cox et al (5579765.)

8. WO 99/24145 discloses a device for detecting needle dislodgement during hemodialysis. As illustrated in figures, the device includes either an adhesive cloth patch 40 having spaced apart resistance members A, B or a layered sensor consisting of spaced apart conductors separated by a hydrophilic cloth layer. The presents of blood caused by a dislodged needle soaks the cloth and completes the circuit. The sensor then triggers the controller to stop the blood pump (page 7, lines 8-18.) Not disclosed by this reference is the loop type resistive sensor.

9. Cox et al discloses a blood leakage sensor. The reference teaches that it is old and well known to use two loop type resistance sensors mounted on a layer of gauze to detect the presents of blood. The reference also teaches that it is old and well known to mount the alarm and transmitter on the patient. This allows the patient and attendants to quickly detect if there is a problem.

10. It would have been obvious to one of ordinary skill in the art to use loop type resistive sensors mounted on a layer of gauze to detect the presents of blood in place of

the resistors in the WO 99/24145 device given Cox et al's teaching that this arrangement is old and well known in the art and since this modification would simplify the design. To locate the alarm and or transmitter on the patient would have been obvious to one of ordinary skill in the art given Cox et al's disclosure that it's old and well known and enables the patient or attendant to quickly notice a problem.

11. Claims 5, 6, 11-14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145 in view of Johnson (5469145.)

12. WO 99/24145 discloses a device for detecting needle dislodgement during hemodialysis. As illustrated in figures, the device includes either an adhesive cloth patch 40 having spaced apart resistance members A, B or a layered sensor comprising two spaced apart conductors separated by a hydrophilic cloth layer. The presence of blood soaks the cloth and completes the circuit. The sensor then triggers the controller to stop the blood pump (page 7, lines 8-18.) Not disclosed by this reference is the capacitive sensor.

13. Johnson discloses a fluid detector. As illustrated in Figures 10-13 the device included a holder (122) and a capacitive sensor. The sensor assembly is releasably attached to the outer layer of the diaper. The device measures the change in capacitance of the cloth layer to record changes in moisture. This feature makes the sensor reusable since it never comes in contact with the fluid.

14. Given Johnson's disclosure it would have been obvious to one of ordinary skill in the art to use a capacitive type sensor in WO 99/24145's device mounted on gauze or

similar material to measure the presents of blood without direct contact thereby making the sensor reusable.

15. Regarding claim 38, as illustrated in Figures 2 and 3 of WO 99/24145 the device includes a cutout portion enabling the sensor to be added *after* the needle has been inserted. Given this, it would have been obvious to one of ordinary skill in the art to position the sensor on the patient *after* the needle is in place since it is one of two obvious and readily apparent possibilities and since this arrangement would allow for a clear unobstructed view of the vein which would not be the case if the sensor was already in place on the patient.

16. Claims 1, 2, 4, 5, 7-10, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (5579765) in view of WO 99/24145.

17. Cox et al discloses a capacitance type blood sensor. The device includes a control device mounted on the patient. The device is used to detect external bleeding. WO 99/24145 discloses a dialysis machine have a blood detector that surrounds the needle. The feature is added to prevent catastrophic blood loss. Given WO 99/24145's disclosures it would have been obvious to one of ordinary skill in the art to use Cox et al's monitor in a dialysis machine given the similar structure and similar intended use.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

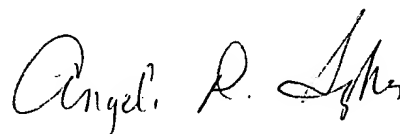
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Joseph S. Machuga
Examiner
Art Unit 3762



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